Amendments to the Claims:

This listing of the claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1 - 249 **(Canceled)**

250. **(Currently Amended)** A method of commercializing at least one previously unreported proprietary method of using ~~use for~~ a product of manufacture or device, wherein the proprietary method of using the product or device is ~~use was~~ established according to the steps comprising:

accessing one or more data sources, wherein at least one data source ~~comprises~~ stores adverse event data associated with the product or device;

analyzing and comparing the stored adverse event data ~~associated with a product of manufacture or device~~, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database, and

then responsive to identifying of the previously unreported essential adverse event, identifying ~~the at~~ at least one previously unreported method of use for the product or device associated with said identified essential adverse event;

documenting inventorship of the at least one previously unreported method of use for the product or device; and

creating a database of proprietary essential adverse event information~~, the database storing data regarding the at least one essential adverse event~~, wherein the database ~~comprises~~ stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, wherein said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, ~~which~~ discloses and relates to at least one of the at least one previously unreported method of use and the at least one essential adverse event, and

wherein the at least one previously unreported proprietary method of using a product or device consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof; and

commercializing the at least one previously unreported proprietary method of using a product or device, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once

identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.

251. **(Currently Amended)** The ~~proprietary~~ method ~~of use~~ of claim 250, ~~wherein the steps of establishing the use~~ further ~~comprise~~ comprises determining value of commercializing the at least one use determined from the at least one identified essential adverse event, wherein the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device.

252. **(Cancelled)**

253. **(Currently Amended)** The ~~proprietary~~ method ~~of use~~ of ~~claim 252~~claim 251, ~~where in the steps of establishing the use,~~wherein the commercializing step further comprises generating information for incorporation into documents for selling, leasing or licensing the identified product information.

254. **(Currently Amended)** The ~~proprietary~~ method ~~of use~~ of ~~claim 252~~claim 251, wherein the product is commercially available at the time of the analyzing step.

255. **(Currently Amended)** The ~~proprietary~~ method ~~of use~~ of ~~claim 252~~claim 251, ~~where in the steps of establishing the use,~~ wherein the step of commercializing further comprises formatting the data relating to at least one adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers

about at least one adverse event associated with exposure to or use of the product or device.

256. **(Currently Amended)** The ~~proprietary~~ method ~~of use~~ of claim 250, wherein the product or device is commercially available at the time of the analyzing step, and ~~where in the steps of establishing the use,~~ wherein the at least one data source comprises information relating to patents and patent applications.

257. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the product or device is commercially available at the time of the analyzing step, and ~~where in the steps of establishing the use,~~wherein the at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

258. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, ~~where in the steps of establishing the use,~~wherein the at least one adverse event comprises a drug interaction.

259. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 258, ~~where in the steps of establishing the use,~~wherein the at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

260. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the steps of establishing the use of the essential adverse event data are proprietary.

261. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the product is medical.

262. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein the product is medical.

263. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 262, wherein the medical product is a generic drug.

264. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the product is non-medical.

265. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein the product is non-medical.

266. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the device is medical.

267. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein the device is medical.

268. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the device is non-medical.

269. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein the device is non-medical.

270. **(Currently Amended)** A proprietary kit containing a product or device, and labeling listing the information which once identified, must accompany the product or device thus notifying a user of at least one previously unreported essential adverse event for the product or device, wherein the ~~kit is used~~ information to be listed

on the labeling is determined in accordance with the ~~proprietary~~ method of ~~use of~~ claim 250.

271. **(Currently Amended)** A proprietary kit containing a product or device, and labeling listing the information which once identified, must accompany the product or device thus notifying a user of at least one previously unreported essential adverse event for the product or device, wherein information to be listed on the labeling is determined ~~the kit is used~~ in accordance with the ~~proprietary~~ method of ~~use of~~ claim 259.

272. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the proprietary method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

273. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 253, wherein the proprietary method of use is a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

274. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the at least one adverse event is a drug interaction.

275. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 274, wherein the product or device is commercially available at the time of the analyzing step.

276. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 275, wherein the proprietary method of use comprises a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to, or use of, the product or device.

277. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 275, wherein at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

278. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 277, wherein at least one previously unreported essential adverse event is other than a chronic immune mediated disorder.

279. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 277, the steps further comprising determining value of commercializing the at least one proprietary method of use determined from the at least one identified essential adverse event, wherein the value depends on a potential value of making a generic product or device into a proprietary product or device, or preventing a proprietary product or device from becoming a generic product or device.

280. **(Cancelled)**

281. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information

relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

282. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein at least one previously unreported essential adverse event comprises a drug interaction, wherein at least one data source comprises information relating to patents and patent applications, and wherein at least one data source comprises information relating to raw commercial or sales data, wherein said raw data is commercial or sales data before being processed and analyzed.

283. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the at least one adverse event data source comprises information regarding product postexposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years.

284. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the at least one adverse event data source comprises information regarding amount of use of the product or device or duration of exposure to the product or device by subjects.

285. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ 250, wherein the at least one proprietary method of ~~use of~~using the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

286. **(Currently Amended)** The ~~proprietary~~ method of ~~use of 252~~ claim 251, wherein the at least one ~~method of use~~ proprietary method of using~~of~~ the product or device is a restricted use in at least one population subgroup, where there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device and the previously unreported essential adverse event is one other than a chronic immune mediated disorder.

287. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

288. **(Currently Amended)** The ~~proprietary~~ method of use~~of~~ claim 251, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

289. **(Cancelled)**

290. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 259, wherein the product or device is commercially available, the steps further comprising identifying the proprietary method of use as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device.

291. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, the steps further comprising documenting date of inventorship and storing information relating to the documented date of inventorship in the database of proprietary essential adverse event information.

292. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein at least one adverse event data source comprises raw data from a plurality of different adverse events, wherein said raw data is commercial or sales data before being processed and analyzed.

293. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the product or device is commercially available, and the proprietary method of use is further identified as comprising restricting exposure of the product or device to at least one factor selected from the group consisting of high temperatures, low temperatures, chemicals, surfaces, pressures, electricity sparks; contact with an anatomical element selected from the group consisting of skin, eyes, ears, respiratory surfaces, gastrointestinal surfaces and mucous membranes of the user; exposure to a subpopulation group selected from the group consisting of children, pregnant women, users with specific allergies, users with specific medical conditions, and animals; exposure to subpopulations defined by at least one user identifying characteristic selected from the group consisting of sex, weight, age, race, genetic characteristics, medical condition, pregnancy status, presence of allergies, use of drugs, use of tobacco, use of alcohol, and use of medical devices.

294. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein at least one database of essential adverse event information is computerized.

295. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, ~~wherein the steps of establishing the use further comprises accessing one or more data sources,~~ wherein at least one data source comprises human adverse event data.

296. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, ~~wherein the steps of establishing the use~~ further ~~comprises~~ comprising utilizing least one controlled clinical trial and or epidemiological study to discover at least one previously unreported essential adverse event.

297. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the step of establishing the adverse event is one other than an abnormal laboratory value.

298. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the use is one other than a new dosing regimen.

299. **(Currently Amended)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the use further comprises providing printed product safety information in connection with product packaging.

300. **(Currently Amended)** The ~~proprietary~~ method of ~~use of claim 252~~claim 251, wherein the use further comprises providing printed product warning information in connection with product packaging.

301. **(New)** The ~~proprietary~~ method of ~~use of~~ claim 250, wherein the step of documenting the inventorship comprises storing information relating to the

documented inventorship in the database of proprietary essential adverse event information.

302. **(New)** A method of commercializing at least one previously unreported proprietary method of using a product of manufacture or device, comprising:

accessing one or more data sources, wherein at least one data source stores adverse event data associated with the product or device;

analyzing and comparing the stored adverse event data, with at least one previously-known adverse event associated with the product or device;

identifying at least one previously unreported essential adverse event associated with the product or device from the adverse event data, wherein an essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database, and

then responsive to identifying of the previously unreported essential adverse event, identifying at least one previously unreported method of use for the product or device associated with said identified essential adverse event;

documenting inventorship of the at least one previously unreported method of use for the product or device; and

creating a database of proprietary essential adverse event information, wherein the database stores at least one record related to at least one of: a patent, patent application, patent publication, or data contained in at least one patent, patent

application or patent publication, wherein said at least one patent, patent application, patent publication, or data contained in at least one patent, patent application or patent publication, which discloses and relates to the at least one previously unreported method of use, and

wherein the at least one previously unreported proprietary method of use consists of a use selected from the group consisting of a restricted use of said product or device, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding an essential adverse event, and any combination thereof, wherein the at least one previously unreported proprietary method of use is not a pharmacogenomic technique for screening; and

commercializing the at least one previously unreported proprietary method of use, the commercializing comprising exclusively disclosing the at least one previously unreported proprietary method of use and the associated at least one previously unreported essential adverse event information, which information, once identified, must then accompany the product or device, wherein commercializing means creating profit from the exclusive disclosure.

303 **(New)** A method of establishing a proprietary previously unknown use for a proprietary or nonproprietary product of manufacture or device, comprising:

accessing one or more data sources, wherein at least one data source comprises data associated with the product or device;

analyzing and comparing the accessed data associated with the product or device to identify at least one previously unreported essential adverse event

associated with the product or device from the adverse event data, wherein the essential adverse event is one regulated by a regulatory agency requiring disclosure of the event in a package insert or data sheet accompanying the product or device, and wherein an essential adverse event is unreported if it has not been reported in any known accessible database,

and then responsive to identifying of the essential adverse event,

identifying essential adverse event information, comprising at least one previously unreported proprietary characteristic or method of use for the product or device specific to the essential adverse event,

wherein the proprietary method of use is selected from the group consisting of providing a restricted use, providing warning(s) about the essential adverse event, providing instruction(s) for avoiding the essential adverse event, and any combination thereof.

304. **(New)** The method of claim 303, further comprising commercializing the identified essential adverse event information, the commercializing comprising exclusively disclosing the proprietary essential adverse event information, which information, once identified, must then accompany the product or device.